

Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The Director, Office of Drug Evaluation II, Office of Review Management, CDER.

(c) The Director and Deputy Director, Division of Metabolism and Endocrine Drug Products, Office of Drug Evaluation II, Office of Review Management, CDER.

(d) The Director and Deputy Director, Office of Compliance, CDER.

(e) The Director and Deputy Director, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

(f) The Team Leader and Assistant, Post-Marketing Surveillance Team, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8319, Feb. 28, 1989; 62 FR 2556, Jan. 17, 1997]

**§ 5.74 Issuance, amendment, or repeal of regulations pertaining to drugs containing insulin.**

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 506 of the Federal Food, Drug, and Cosmetic Act regarding the issuance, amendment, or repeal of regulations pertaining to drugs containing insulin:

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The Director, Office of Drug Evaluation II, Office of Review Management, CDER.

(c) The Director and Deputy Director, Division of Metabolism and Endocrine Drug Products, Office of Drug Evaluation II, Office of Review Management, CDER.

(d) The Director and Deputy Director, Office of Compliance, CDER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8319, Feb. 28, 1989; 62 FR 2557, Jan. 17, 1997]

**§ 5.75 Designation of official master and working standards for antibiotic drugs.**

The following officials are authorized to designate official Food and Drug Administration master and working standards for antibiotic drugs under § 430.5 of this chapter:

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Office of Testing and Research, Office of Pharmaceutical Science, CDER.

(c) The Director and Deputy Director, Division of Research and Testing, Office of Testing and Research, Office of Pharmaceutical Science, CDER.

[49 FR 27315, July 3, 1984, as amended at 54 FR 8319, Feb. 28, 1989; 62 FR 2557, Jan. 17, 1997]

**§ 5.76 Certification of antibiotic drugs.**

The following officials are authorized to certify or reject batches of antibiotic drugs, or any derivative of these drugs, pursuant to sections 507(a) and 512(n) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Office of Compliance, CDER.

(c) The Director and Deputy Director, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

(d) The Team Leader and Assistant, Post-Marketing Surveillance Team, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8319, Feb. 28, 1989; 62 FR 2557, Jan. 17, 1997]

**§ 5.78 Issuance, amendment, or repeal of regulations pertaining to antibiotic drugs.**

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 507 of the Federal Food, Drug, and Cosmetic Act (the act) regarding